REMARKS

Applicants' invention, as delineated by pending claims 1-9, 11-16, 18-19, and 22-24, is directed to a surgical implement detection system for detecting surgical implements within a wound at the conclusion of a surgical procedure. Compared to previously-known markers for article detection systems, the present inventive marker has a significantly reduced size. As a result, the marker is readily attached or similarly associated with surgical implements, including both reusable surgical tools, disposable items such as surgical sponges, or other like articles. The marker's smaller size permits it to be attached to items that otherwise could not be protected. In some cases, a surgical item is simply too small to accommodate a conventional marker. The item may be smaller than the typical 1.5" length of a marker operative at about 60 kHz, or it may have no suitable location large enough for such a marker to be placed on it. In other instances, a conventional marker accompanying an item or attached to it would be an impediment to the item's ordinary use, e.g. by interfering with a surgeon's manipulation of the item. Applicants maintain that the prior art has failed to recognize the potential for a smaller, more widely applicable marker that could avoid these detriments.

The problem of implements left behind after the completion of surgical procedures remains a serious and vexing medical issue, because if undetected, these items are highly likely to cause serious, and possibly fatal, injury to a patient. The present system provides a procedure whereby these items can be reliably, quickly, and efficiently detected in the harried and intense environment of an operating room, even prior to the completion of the surgical procedure and closure of the surgical wound, thereby avoiding the risk of infection and other injury to the patient, and obviating the need for further invasive, deleterious, and painful follow up care otherwise inexorably required.

The Examiner has rejected claims 1-5, 14-16, 18, 19, and 22 under 35 USC 102(b) as being anticipated by or, in the alternative, under 35 USC 103(a) as obvious over US Patent No. 5,057,095 to Fabian, which discloses a surgical implement detector utilizing a resonant marker. In one embodiment, the Fabian marker is magnetomechanical.

With respect to claims 1, 12, and 13, the Examiner has indicated that Fabian teaches a system for detecting surgical implements using a magnetomechanical marker having a resonant frequency. The range of operation of the system is said to be below about 1 GHz. It is further indicated that the operation of the Fabian system may rely on any of three types of resonance, viz. magnetomechanical, electromechanical, and electromagnetic.

It is axiomatic that a novelty rejection is proper only if every feature of the claims is disclosed in a single reference. The Examiner has acknowledged that Fabian et al. fails to expressly disclose applicants' claimed frequency ranges, admitting that the only guidance provided by Fabian et al. the system operates at a "conventional" frequency. Accordingly, the Examiner has pointed to disclosure by Von Hoene et al. of a magnetomechanically resonant element said to have a resonant frequency of 120.21 kHz, which is alleged to support a position that the "conventional system" disclosed by Fabian employs a resonant frequency of 120.21 kHz.

Applicants respectfully continue to maintain that Von Hoene et al. cannot properly be used in the manner that Examiner has delineated, specifically traversing the propriety of using the later-filed Von Hoene et al. reference to establish any frequency range as being what Fabian et al. meant by the term "conventional." In particular, it is submitted that the citation of Von Hoene et al. does not satisfy any of the three narrow situations set

forth in MPEP 2131.01 in which multiple references are properly employed in a rejection under 35 USC 102.

The Examiner has apparently equivocated as to which of the three circumstances of MPEP 2131.01 predicates the citation of Von Hoene et al. At page 10, first line, of the instant Office Action, he has contended that the reference is proper to show enabled disclosure (Circumstance I). On the other hand, at page 2, four lines from the end, the Examiner states that he "has looked to the prior art to try to determine what resonant frequency is for a conventional system" (Circumstance II). There is no indication that the Examiner has invoked Circumstance III ("to show that a characteristic not disclosed in the reference is inherent"), and applicants maintain it is not pertinent. Clearly, the frequency of a conventional EAS system cannot be regarded as an inherent characteristic common to all EAS systems, e.g. in the sense of a scientific truism.

Applicants further maintain that Circumstance I cannot properly be invoked. MPEP 2131.01 indicates that additional references may be adduced to show that the disclosure of the primary reference was enabled as of the time of the invention for which a patent was sought. Significantly, the instance cited was one in which "the claimed composition or machine is disclosed identically by the reference." However, in the present instance, no composition or machine is disclosed identically by the Fabian et al. reference, because the particular frequency range recited by claim 1 was not identically disclosed. Consequently, the issue is not one of enablement, but rather Fabian's understanding of the meaning of the term "conventional," for which only Circumstance II is pertinent.

Applicants respectfully point further to the following statement made in MPEP 2131.01 with respect only to Circumstance III: "Also note that the critical date of extrinsic evidence showing a universal fact need not antedate the filing date. See MPEP

§ 2124." (emphasis added). As best understood by applicants, the Examiner has apparently, but improperly relied on this statement in the different context of Circumstance II. While a "universal" fact is, by its nature, timeless, and so amenable to demonstration at any point in time, a contingent fact, such as what is "conventional" in a particular article detection system, is clearly not universal or timeless. Significantly, nothing in the discussion of Circumstance II in MPEP 2131.01 supports the propriety of a later reference to elucidate the meaning of a term in a primary reference.

Accordingly, applicants maintain the Examiner's use of Von Hoene et al. in the proffered novelty rejection is untenable.

In the present instance, the Examiner thus has used the Von Hoene et al. reference under circumstance II, to explain the meaning of the term "conventional" with respect to the operating frequency of a magnetomechanical EAS system. However, to demonstrate anticipation, it must be established that Fabian et al. used the critical term in the manner asserted by the Examiner. That is to say, it must be established that such frequencies were recognized as conventional at the time of the filing of Fabian et al., because the art's understanding of a term such as "conventional" can clearly be fungible. The Von Hoene et al. reference cannot establish such a fact because of its later date. In particular, the Fabian et al. patent was filed on November 16, 1989. At best, VonHoene et al. has an earliest claim to priority as of the August 20, 1991 filing of parent application Serial No. 07/747,767. It is thus submitted that Von Hoene et al. cannot properly be used to establish what was a "conventional" system as of the filing date of the earlier-filed Fabian patent. Absent such a showing, it is submitted that claims 1, 12, and 13, which recite a range of 70-300 kHz, cannot properly be regarded as anticipated by Fabian. Applicants maintain the foregoing arguments with respect to the claimed 70-300 kHz range apply with equal force to independent claims 2, 14, and 22, rendering them novel

over Fabian for at least the same reasons. Claims 3-5, 15-16, and 18-19, being dependent (directly or indirectly) from independent claims 2, 14, and 22, are likewise submitted to be patentably novel.

Such a range is clearly not disclosed by Fabian, nor can Von Hoene et al. be regarded as pertinent. Applicants accordingly maintain that the disclosure of the 70-300 kHz is not made with sufficient specificity in Fabian to satisfy the test under *Ex parte Cole*, 2001 WL 1918535 (BPAI, 2001), quoting *Ex parte Lee*, 31 USPQ2d 1105, 1107 (BPAI, 1993). ["Where, as here, a reference describes a class of compositions, the reference must be analyzed to determine whether it describes a composition(s) with sufficient specificity to constitute an anticipation under the statute. *Ex parte Lee*, supra, at 1106-1107, emphasis added, citing *In re Schaumann*, 572 F.2d 312, 197 USPQ 5 (CCPA 1978).]

The Examiner has alternatively rejected claims 1-5, 12-16, 18, 19, and 22 as being obvious over Fabian.

Applicants continue to maintain that nothing in the Fabian reference would suggest a magnetomechanical marker wherein the resonant element has a resonant frequency in the range of about 70 to 300 kHz. As set forth at page 8, line 19 to page 9, line 3; page 18, lines 1-15; and page 18, line 23 to page 19, line 10, a marker constructed to operate within such a frequency range advantageously is smaller in size than conventional magnetomechanical markers used in connection with a surgical implement, such as that disclosed by Fabian, but nevertheless has an adequate volume of magnetic material to emit a signal that is large enough to permit highly reliable, rapid detection of the marker in the adverse environment of surgery. There is nothing in Fabian et al. to suggest such a reconstruction. Clearly, speed and reliability of detection are of paramount importance in

such a situation. On the other hand, increasing the operating frequency of the detection system necessarily decreases the length of the resonant element of the marker. In addition, the reducing the length also typically necessitates decreasing the width of the element in order to maintain a comparable demagnetizing factor. The decrease in total element volume in turn inherently reduces the signal output the marker provides. The prior art has thus eschewed shorter, higher frequency markers, regarding them as providing inadequate output to permit reliable marker detection. On the other hand, applicants' marker is capable of providing sufficient output as a result of the particular configuration taught.

Advantageously, the compact size of the present marker permits surgical items to be tagged that would be physically impossible to tag using larger conventional markers. As set forth above, many surgical items either do not have a suitable location on which to situate a conventional marker, or the use of the item would be adversely impacted by the presence of the marker. On the other hand, the smaller markers provided by applicants can be used beneficially in such situations.

Moreover, applicants submit that nothing in Fabian would lead a skilled artisan to the particular frequency range required by applicants' claims. Such a range surprisingly and unexpectedly permits the present magnetomechanical technology to be extended to a far wider range of surgical implements than would be possible using the much larger prior-art tags needed for operation at conventional magnetomechanical frequencies. Such lack of disclosure even further rebuts any purported conclusion that Fabian provides the requisite level of specificity of disclosure. ["If the claims are directed to a narrow range, the reference teaches a broad range, and there is evidence of unexpected results within the claimed narrow range, depending on the other facts of the case, it may be reasonable to conclude that the narrow range is not disclosed with 'sufficient specificity' to

constitute an anticipation of the claims. The unexpected results may also render the claims unobvious." MPEP 2131.03 (II).]

Applicants thus maintain that Fabian fails to disclose or suggest every feature delineated by independent claims 1, 2, 14, and 22. Even less does Fabian disclose or suggest every feature of dependent claims 2-5, 15-16, 18, and 19, as amended which are submitted to be novel for at least the same reasons as claims 1, 2, 14, and 22.

In view of the foregoing remarks, it is submitted that the system of claims 1-5, the method of claims 14-16 and 18-19, and the surgical implement of claim 22 are novel and unobvious over Fabian.

Accordingly, reconsideration of the rejection of claims 1-5, 14-16, 18-19, and 22 under 35 USC 102(b) as being anticipated by or, in the alternative, under 35 USC 103(a) as obvious over Fabian is respectfully requested.

Claims 1-5, 12-16, 18, 19, and 22 were rejected under 35 USC 103(a) as being unpatentable over Fabian in view of US Patent No. 5,338,373 to Von Hoene et al.

The Von Hoene et al. reference is directed to a method of encoding and decoding a glassy alloy strip to be used as an identification marker. Attention is further drawn to the disclosure at col. 4, lines 18-24, in which the patentees state that "The fundamental aspect of this invention is that the modification to the alloy strip be of such a nature as to change the effective length of the marker. The effective length of an alloy strip may be calculated for a modified strip by using the physical length and resonant frequency of an unmodified strip having the same composition."

As noted hereinabove in connection with the rejection over Fabian, the Examiner has acknowledged that Fabian's disclosure does not provide numerical values of the frequency of the magnetomechanical markers, beyond the generic disclosure of "below 1

gigahertz" and the statement that the resonant frequency is one used by a conventional system. As further set forth hereinabove, nothing in the record establishes that Fabian contemplated any operation of a conventional magnetomechanical system at a frequency in the claimed 70-300 kHz range, let alone a preferred system operating in the ranges 110-250 kHz or 120-200 kHz. While Von Hoene et al. admittedly discloses in Table I a magnetomechanically resonant strip having a resonant frequency of 120.21 kHz, it is submitted that such disclosure falls short of rendering obvious the use of such a strip in a marker appointed for an EAS system, let alone a marker attached to a surgical instrument so as to render such instrument detectable in the manner provided by applicants' invention. The object of the Von Hoene et al. invention, to the contrary, is to provide a large plurality of unique and measurably discernable markers (see, e.g., col. 2, lines 46-59), wherein the resonant frequency is determined by the effective length of a marker element, not the actual length. Nothing in Von Hoene et al. contemplates or suggests the use of any marker having a 120.21 kHz resonant frequency, let alone such a marker in a medical or surgical context. To the contrary, the various techniques for modifying the effective length of marker disclosed by Von Hoene et al. were all implemented using markers having a resonant frequency of about 55-69 kHz, as provided in Examples 2-7. The Examiner has suggested that Von Hoene et al. teaches changing the length of the marker. However, he has relied on a passage that relates to changes in effective length resulting from particular processing and not from changes in the actual length of the marker element.

By way of contrast, the present invention provides a marker attachable to a surgical instrument, the marker being of significantly reduced size compared to conventional markers operating at lower frequency. As a result, the marker enables the reliable, quick, and efficient detection of retained instruments in the harried and intense

environment of an operating room, even prior to the completion of the surgical procedure and closure of the surgical wound, thereby avoiding the risk of infection and other injury to the patient, and obviating the need for further invasive, deleterious, and painful follow up care otherwise inexorably required. The small size further permits instruments to be tagged that could not be tagged with larger prior art markers. None of these beneficial attributes is afforded by any marker or tagged instrument constructed in accordance with the teachings of Fabian and Von Hoene et al., even if taken in combination.

It is thus respectfully submitted that even in combination, Fabian and Von Hoene et al. do not disclose or suggest the system delineated by applicant's claims 1-5, 12-13, the method of claims 14-16, 18, and 19, or the surgical implement of claim 22, as amended.

Accordingly, reconsideration of the rejection of claims 1-5, 12-16, 18, 19, and 22 under 35 USC 103(a) as being unpatentable over Fabian in view of VonHoene et al. is respectfully requested.

Claims 6, 7, and 11 were rejected under 35 USC 103(a) as being unpatentable over the combination of Fabian and VonHoene et al. as applied to claims 1-5 above and further in view of US Patent No. 6,359,563 to Herzer, which provides a magneto-acoustic marker for electronic article surveillance having reduced size and high signal amplitude.

Significantly, the reduction in size afforded by Herzer is attained by use of narrower magnetostrictive ribbon, e.g. ribbon 6 mm wide instead of the 12.7 mm wide ribbon that is said to be conventional. The resonant element in Herzer remains rectangular, with no recognition of shortening the long dimension of the marker, which is typically about 1.5 inches as required to maintain an operating frequency of about 55-60 kHz.

The Examiner has contended that that Herzer teaches use of a plurality of resonator pieces to allow the width of the marker to be reduced. As set forth above, Herzer does not cure the lack of disclosure or suggestion of the 70-300 kHz range in the combination of Fabian and VonHoene et al.,

It is thus respectfully submitted that even in combination, Fabian, VonHoene et al., and Herzer do not disclose or suggest the system delineated by applicant's claims 6, 7, and 11, as amended.

Accordingly, reconsideration of the rejection of claims 6, 7, and 11 under 35 USC 103(a) as being unpatentable over Fabian and VonHoene et al. in further view of Herzer is respectfully requested.

Claims 8, 23, and 25 were rejected under 35 USC 103(a) as being unpatentable over the combination of Fabian, VonHoene et al., and Herzer as applied to claims 6-7 above and further in view of US Patent Publication No. 2002/0005783 to Irrizary et al., which provides a child monitoring device.

As set forth above, even the combination of Fabian, VonHoene et al., and Herzer fails to suggest the 70-300 kHz range required by each of claims 8, 23, and 25. Irrizary et al. further fails to cure this deficiency.

The Examiner has acknowledged that the foregoing combination fails to teach a marker wherein a plurality of elongated strips is not disposed in parallel, and so has cited Irrizary et al. Applicants respectfully point out that Irrizary et al. fails to disclose or suggest any embodiment in which the plural, non-parallel strips are disposed in a single cavity. Instead, Irrizary et al. provides a marker that is a combination of two separate markers, with the respective resonant elements disposed in <u>different</u> cavities. Such a marker is inherently more complicated and difficult to construct, and entails use of more

bias elements than needed in the present marker. As a result, it is submitted that there is no motivation for the substantial reconstruction that would be needed to reach the present claimed structure.

More specifically, applicants respectfully submit that the tag of Irrizary et al. comprises two magnetomechanical markers, having elongated axes that are perpendicular. Whereas each of the mechanical markers (e.g. markers 25 and 26 of tag 21 shown in Fig. 2) of Irrizary et al. separately includes a magnetomechanical elongated strip, applicant's marker includes a magnetomechanical element comprising a plurality of elongated strips. As set forth by claim 4, feature (c), on which claim 8 depends through claim 6, a housing encloses the magnetomechanical element and the bias means. Claim 6 expressly recites that the housing includes a cavity in which the plurality of elongated strips are disposed. Claim 23 similarly recites a marker including one cavity and a plurality of strips disposed in that cavity. Claim 25 calls for the marker to have a housing and a cavity therein and a plurality of elongated strips disposed in the cavity in a non-parallel orientation. Therefore, it is respectfully submitted Irrizary et al. does not disclose a marker wherein a magnetomechanical element comprises plural strips that collectively constitute a magnetomechanical element and are together enclosed in a housing. Rather, the Irrizary et al. marker comprises multiple magnetomechanical elements that are enclosed in cavities in separate housings, even if the multiple markers are mechanically joined. Irizzary et al. further fails to disclose or suggest the particular resonant frequency range delineated by applicants, thereby failing to cure the aforementioned deficiency, even if all the applied references are taken in combination.

It is thus respectfully submitted that even in combination, Fabian, VonHoene et al., Herzer, and Irrizary et al. do not disclose or suggest the system delineated by applicant's claim 8, the surgical implement of claim 23, or the method of claim 25, as amended.

Accordingly, reconsideration of the rejection of claims 8, 23, and 25 under 35 USC 103(a) as being unpatentable over Fabian, VonHoene et al., and Herzer in view of Irrizary et al. is respectfully requested.

Claims 9 and 24 were rejected under 35 USC 103(a) as being unpatentable over the combination of Fabian, VonHoene et al., Herzer, and Irrizary et al. and further in view of US Patent 6,407,676 to Tanji et al.

Tanji et al. provides a magnetostrictive resonator appointed to be embedded in a roadway for use in connection with a vehicle detection system.

The Examiner has acknowledged that the combination of Fabian, VonHoene et al., Herzer, and Irrizary et al. fails to disclose a configuration having magnetomechanical strips on either side of a bias magnet, but has contended that Tanji et al. teaches placing resonators on both sides of the bias magnet to allow the marker to be made smaller.

However, applicant respectfully submits that even in combination, Fabian, VonHoene et al., Herzer, Irrizary et al., and Tanji et al. fail to teach the claimed frequency range of about 70 to 300 kHz, as delineated by claims 1, 2, 14, and 22, on which claims 9, 11-13, and 24 depend. Accordingly, it is submitted that claims 9, 11-13, and 24 are patentable for at least the same reasons as claims 1, 2, 14, and 22, as set forth hereinabove.

Moreover, as set forth in conjunction with the rejection of claims 6, 7, and 11 over Fabian, VonHoene et al., and Herzer, the use of plural bias strips in the manner of either Herzer, Irrizary et al., or Tanji et al. at best permits a marker to be narrowed in its width dimension. Such narrowing does not affect the required length dimension, which must still be maintained because of the selection of the particular resonant frequency employed by conventional systems, e.g. about 60 kHz. Especially in embodiments in which parallel

strips are used, the length dimension is necessarily dominant. See, e.g., Von Hoene et al. at col. 4, lines 5-7. Nothing in any of the cited references addresses this limitation or suggests the desirability of a medical implement detection system employing shorter markers. None the aforementioned benefits of such a system for surgical instrument detection is afforded by any marker or system constructed in accordance with the combined teachings of Fabian, VonHoene et al., Herzer, Irrizary et al., and Tanji et al.

Accordingly, reconsideration of the rejection of claims 9 and 24 under 35 USC 103(a) as being unpatentable over Fabian, VonHoene et al., Herzer, and Irrizary et al. and further in view of Tanji et al. is respectfully requested.

In view of the foregoing remarks, it is respectfully submitted that the present application has been placed in allowable condition. Reconsideration of the rejection of claims 1-9, 11-16, and 18-25, entry of the present amendment, and allowance of the present application are earnestly solicited.

Respectfully submitted,

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